UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,901	08/24/2001	Seiki Kuramitsu	11283-013001	5458

7590 07/16/2003

GREGORY P. EINHORN
Fish & Richardson P.C.
Suite 500
4350 La Jolla Village Drive
San Diego, CA 92122

EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1636	6

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,901	KURAMITSU ET AL.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 32 drawn to isolated protein or fusion protein and methods of expressing comprising SEQ ID NO. 2,4,6 and 8, classified in class 530, subclasses 351 and 412.

II. Claims 4-14, 17-23 and 30, drawn to nucleic acids, vectors and host cells and methods of expressing comprising SEQ ID 1,3,5 and 7 and methods of expressing, classified in class 435, subclass 69.1.

III. Claims 15-16 drawn to methods of repairing DNA and preventing errors, classified in class 435, subclass 91.1.

IV. Claim 24-25 drawn to an array comprising SEQ ID NO. 1 and 4-7, classified in 435, subclasses 174 and 287.2.

V. Claim 26 drawn to a method of screening a composition, classified in 435, subclass 7.1.

VI. Claim 27-29 drawn to a method of inhibiting the expression of a DNA repair enzyme, classified in class 435, subclass 701.

VII. Claim 31 drawn to a method for detecting nucleic acids, classified in class 435 subclass 6.

VIII. Claims 33-35 drawn to an isolated antibody classified in class 435, subclass 130.1.

The inventions are distinct each from the other because of the following reasons:

Each group within Groups I-VIII reads on patentably distinct DNA constructs or encoded proteins comprising one of unrelated SEQ ID numbers 1-8. Each sequence is patentably distinct because they are unrelated sequences. For each of Groups I-VIII, Applicants must elect a single sequence for examination. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996) e.g.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, select to a restriction requirements pursuant to 35 U.S.C. 1121 and CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry to protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

It has been decided that, due to the high burden placed on the Office to search sequences, ONE sequence constitutes a reasonable number for examination purposes. Applicant is required to elect ONE independent and distinct sequence. Examination will be restricted to only the one elected sequence. The search of no more than one selected sequences may include the complements of the selected sequence and where appropriate, may include subsequences within the selected sequence (i.e. oligomeric probes and/or primers).

It is noted that the claims recite the sequences are cited in a Markush format. Restriction to one SEQ ID number is still appropriate here because the members of the Markush group lack unity of invention in that they do not share a substantial structural feature disclosed as being essential to the recited utility (See MPEP 803.02).

The invention of group I is unrelated to the inventions of group II, IV and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the nucleic acids, proteins, arrays and antibodies of group I, II, IV and VIII are related in that they are drawn to SEQ ID Nos 1-8. However, they are distinct inventions because they are drawn to chemically distinct products with distinct functions and modes of operation. For example, the proteins of group I have a distinct and different function from the nucleic acids of group II and can be made by another and materially different process such as synthetic peptide synthesis or purification from another source. The proteins of group I are related to the antibodies of group VIII by virtue of being the cognate antigen, necessary for the production of the antibodies. They are distinct inventions because they are functionally and physically distinct chemical inventions and because the protein can be used in a materially different process from the production of the antibody such as in a pharmaceutical composition.

The methods of inventions II-III and V-VII are unrelated to each other. The methods utilize distinct and separate method steps and have distinct outcomes. The methods of group II is unrelated to groups III, V, VI or VII and are directed to methods that recite structurally and functionally distinct elements, are not required one for the other and achieve different goals. Groups I and II produce a DNA repair enzyme with steps of cell growth in culture and protein recovery that are not required for DNA repair (group III), for screening compositions (group VI) or for the detection of nucleic acids (group VII). The invention of group III requires DNA synthesis methods that are not required for any of the methods of groups VI-VII and the product

of group III, repaired DNA, is not used in any other invention. The method of group V, screening for a composition that binds to a DNA repair enzyme, requires the distinct steps of preparing a composition and steps of screening the composition for DNA repair activity. As well, the composition of group V is not used in any other invention. The outcome of group VI, inhibiting the expression of a DNA repair enzyme, is an opposite outcome from that of groups I and II and a distinct outcome from that of group III and V and VII. The method of group VI utilizes distinct steps of identifying and using antisense DNA to block the activity of a DNA repair enzyme. The method of group VII requires the steps of hybridization to and detection of nucleic acids in a sample to identify genes that are not used in any other invention

While the inventions of groups I-II and groups III-V-VI-VII are related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05 (h)). In the instant case, the vectors and nucleic acids of group II can be used as an expression system for the production of pure protein and the protein may be used for the production of antibodies, the array can be used to assay the changes in gene expression related to SEQ ID No: 1, 3, 5 and 7 and the antibodies can be used for immunohistochemistry.

These inventions are distinct or the reasons given above and have acquired a separate status in the art as shown by their different classification 530/351 (Group I) versus 435/69.1 (Group II) versus 435/91.1 (Group III) versus 435/174 (Group IV) versus 435/7.1 (Group V) versus 435/701 (Group VI) versus 435/6 (Group VII) versus 435/130.1 (Group VIII) and their

recognized divergent subject matter. The searches required for the different groups are not coextensive; a search for art pertaining to methods for cloning promoters is not coextensive with a search for art pertaining to methods of regulating gene expression and protein production. Therefore, restriction for examination purposes as indicated is proper.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter.

Applicant is reminded that upon cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Maria B Marvich, PhD
Examiner
Art Unit 1636

July 14, 2003

PATENT EXAMINER